SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF MICHIGAN

FINALLY Crafting "Those Wise Restraints that Make Us Free"

A Road-Map for Precautionary and Humane Cost-Benefit Decision-Making at EPA

EPA Brain Trust
Via Social Distance, USA
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("Law and Liberty" website)

Biden Lets Slip the Dogs of Regulation

THE FIRST MONTH OF PRESIDENT BIDEN'S ADMINISTRATION BEGAN

— PEGGY LITTLE

Another presidential memo, issued on January 20, 2021, is called "Modernizing Regulatory Review." This one instructs the powerful Office of Management and Budget—which oversees *all* federal agencies—on how to account for the costs and benefits of regulation, a process which has long served as a check on regulatory power. Some estimates of the costs of regulation suggest that they may be as high as $1.9 trillion. Such regulation operates as a hidden and deeply ingrained tax upon Americans. Under the new OMB policy, agencies are ordered to ensure that the cost-benefit review process "fully accounts for regulatory benefits that are difficult or impossible to quantify." This is Newspeak for "put the regulatory thumb on the benefits pan of the scale and jettison rigorous cost-accounting." The memo instructs agencies to use the regulatory review process to "promote public health and safety, economic growth, social welfare, racial justice, environmental stewardship, human dignity, equity, and the interests of future generations"—all immeasurables. This can only be described as a blank check for runaway regulation.

My Core Beliefs in this Area:

- Regulations (and "soft law" goals) should *primarily* be determined by the results of cost-benefit analysis (CBA); purported alternatives (P2, feasibility analysis, etc.) are either less rational, less protective, or both.
- The statement above only *sounds like* a centrist or a right-wing position because the environmental movement has "missed the boat" on CBA for decades; CBA's failings are failings of practitioners, not of the method.
- But CBA has always been biased, in both broad and narrow ways, ***against*** needed controls, and it is getting "worse" in this regard. *We are being gaslit by "experts" who claim that risk assessment and CBA exaggerates risk and underestimates cost– in both respects, I and others have shown, the opposite is generally true.*
- So, before I talk about what Vicki asked me to talk about (EPA's opportunity under the Biden "Day 1 Memo" to embrace "benefits that are difficult to quantify"), I want to mention some of the **hard-to-see thumbs on the scale" that EPA must remove first.**

Regulatory Analysis and Reg'y Design are not Friendly Enough to Health/Envt.:

- *Every* balance between over-estimation of net benefit (NB) vs. under-estimation is value-laden; do not be gaslit that only expected values are "objective" or value-neutral– they are optimal only under *very* strict conditions.
- Put another way, have we been catering more to public fears about pollution or to *private fears about expenditures?* There are two kinds of "precautionary principles" out there…
- Put still another way, you don't work for the "Environmental Prediction Agency"
- So, many of the things we take for granted are actually thumbs on the scale <u>against</u> stringency:
    - ❖ Choosing controls for which B>C, when there are other options for which B>>C, and still others for which [*more* B] still exceeds [more C];
    - ❖ "Cost-effective" is always (mis)defined as the cheapest way to get a given amount of benefit– this is NOT "the most bang for the buck," but "the least buck for the bang"! (we need "the most beneficial way to spend up to a given cost")
    - ❖ Critics have come up with illogical "serious" ideas like the regulatory budget (an annual cost ceiling), when what we need more is an annual "benefits floor"!
    - ❖ SBREFA panels empower one side (fine), but why not *also* a panel of those *affected* by small businesses?

And, of course, virtually all of the tens of thousands of objections OIRA staff and its Administrator have raised over the past 40 years to EPA's (and OSHA's, and others') regulatory proposals– *including in Democratic administrations*– have asked "can we do almost as much good for less money?"

Never "can we do much more good for a bit more money?"

This bias needs to end.

Analytic Recommendations for EPA 2021–ff., in Five Broad Areas:

1. Capturing important categories of benefits (finally);
2. Correcting underestimation of those benefits that are already captured;
3. Ensuring EPA doesn't overestimate benefits;*
4. Capturing important categories of *costs*** (finally); *and*
5. Correcting underestimation of costs (and overconfidence about them!)

* it's important to look even-handedly for gaps/problems in CBA, not to only fix problems that have led to insufficient protections.

**note that I prefer to define "benefits" as changes, *positive and negative,* in non-market good like longevity, and "costs" as changes, *positive and negative,* in economic welfare.

Capturing Important Categories of Hard-to-Quantify (HTQ) Benefits:

- Most importantly, the point of doing this is *not* merely to be able to say "See? This control option has even more net benefit than we thought." It is to impel the search for *more stringent controls* that still have positive net benefit!

- Suppose that the best EPA can do is put wide uncertainty bounds around an HTQ benefit, and is forced by political realities to use the LOWER confidence limit on this range as the contribution to total benefits. This is *still* less arbitrary, and more precautionary, than counting as zero something we KNOW to be > zero.

- Bayesian methods are tailor-made for the use of weak prior distributions that can readily be narrowed as more data become available.

Important "Missing Benefits":

- Virtually ALL (see next slide) of the grave health effects other than cancer;
- "Minor" tumor types found in bioassays or epidemiologic studies;
- "Minor" health effects that don't command attention (e.g., adult hypertension & MeHg);
- Environmental amenities (more stated-preference studies needed);
- IF (see below) interesting exculpatory theories are given some quantitative weight, then we should consider counting "the 94% chance that a negative epidemiology study may reveal a true association";
- Risks reduced to WORKERS, which often dwarf the primary benefits to the community.

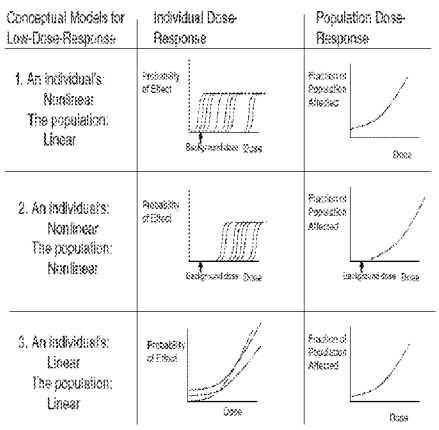


FIGURE 5-10 Examples of conceptual models to describe individual and population dose-response relationships.

(from National Academy of Sciences **Science and Decisions** report, 2009)

BOX 5-3 Calculating a Risk-Specific Dose and Confidence Bound in Conceptual Model 2

I. Derivation of Human POD

Human POD = (Animal POD)/$F_{A\to H\ POD\ adjust}$ = (Animal POD)/($F_{A\to H} \times F_{SC\to C} \times F_{Gap}$)
log (Human POD) = (log Animal POD) – (log $F_{A\to H}$ + log $F_{SC\to C}$ + log F_{Gap})
$\sigma^2_{log\ F\ Human\ POD} = \sigma^2_{log\ F\ Animal\ POD} + \sigma^2_{log\ F\ A\to H} + \sigma^2_{log\ F\ SC\to C} + \sigma^2_{log\ F\ Gap}$

Assume:

Data gap is inconsequential:
$F_{Gap} = 1$, $\sigma_{log\ F\ Gap} = 0$

Subchronic-to-chronic per Hattis et al. 2002:
50th percentile for $F_{SC\to C} = 2$, $\sigma_{log\ F\ SC\to C}$ = log [2.17] = 0.34

Animal to human adjustment per Hattis et al. (2002) for sodium azide:
50th percentile for $F_{A\to H}$ 3.85, 95% upper bound 18.5, thus $\sigma_{log A\to H}$ = log(18.5/3.85)/1.645 = 0.42 (Division by the 95% confidence bound is 1.645 standard deviations from the median in the standard normal distribution.)

Variability in animal POD:
lower 95% bound 2-fold difference from median; thus $\sigma_{Animal\ POD}$ = log(2)/1.645 = 0.18
⇒ Overall variability in human POD: $\sigma^2_{Human\ POD}$ = $0.34^2 + 0.18^2 + 0.42^2 = 0.32 = 0.57^2$

For animal POD (ED_{05}) of 1 mg/kg-d:
Human median POD (ED_{50}) = $1/(F_{A\to H}F_{SC\to C}F_{Gap})$ = 1/(2 × 3.85 × 1) = 0.13 mg/kg-d

Lower 95% confidence bound on human POD
= (median Human POD)/$10^{(1.645)(log\ Human\ POD)}$ = $0.13/10^{(1.645)(0.57)}$ = 0.015 mg/kg-d

II. Derivation of Risk-Specific Dose

Interindividual PK/PD variability (assume Hattis et al. 2002 distribution):
$\sigma_{log H}$ = 0.476 (This estimate also is uncertain, with geometric standard deviation of 1.45)
The 10^{-5} individual is 4.25 standard deviations from the estimated human ED_{50}:
$10^{(4.25)(0.476)}$ = 105

Median human dose with 10^{-5} risk:
(Median POD)/105 = 0.13/105 = 0.0012 mg/kg-d
Lower 95% bound on human dose with 10^{-5} risk: 0.006 µg/kg-d (This is calculated using a Monte Carlo procedure. It takes into account $\sigma_{Human\ POD}$ and the uncertainty in $\sigma_{log H}$.)

Problems Created by the Failure of Congress and EPA to Define "Unreasonable Risk" in TSCA, and by EPA's Refusal to even Estimate Risks for Non-Cancer Effects:

"Historically, dose-response assessments at EPA have been conducted differently for cancer and non-cancer effects, and the methods have been criticized for not providing the most useful results. Consequently, non-cancer effects have been underemphasized, especially in benefit-cost analyses. A consistent approach to risk assessment for cancer and non-cancer effects is ***scientifically feasible and needs to be implemented.***

-from NAS *Science and Decisions* report, 2009

"Unreasonable Risk" is mentioned 20 times in the Lautenberg Act but not ONCE defined.

The most important aspect of a proper unreasonable-risk definition is that it should come to us in units of risk! EPA has failed for more than 40 years to express risks for non-cancer health effects in units of risk, instead falling back on outmoded concepts such as the "margin of exposure" or the "reference dose." These are *not* conclusions about risk, but rather are assertions (somewhat or wholly arbitrary ones) of "safety."

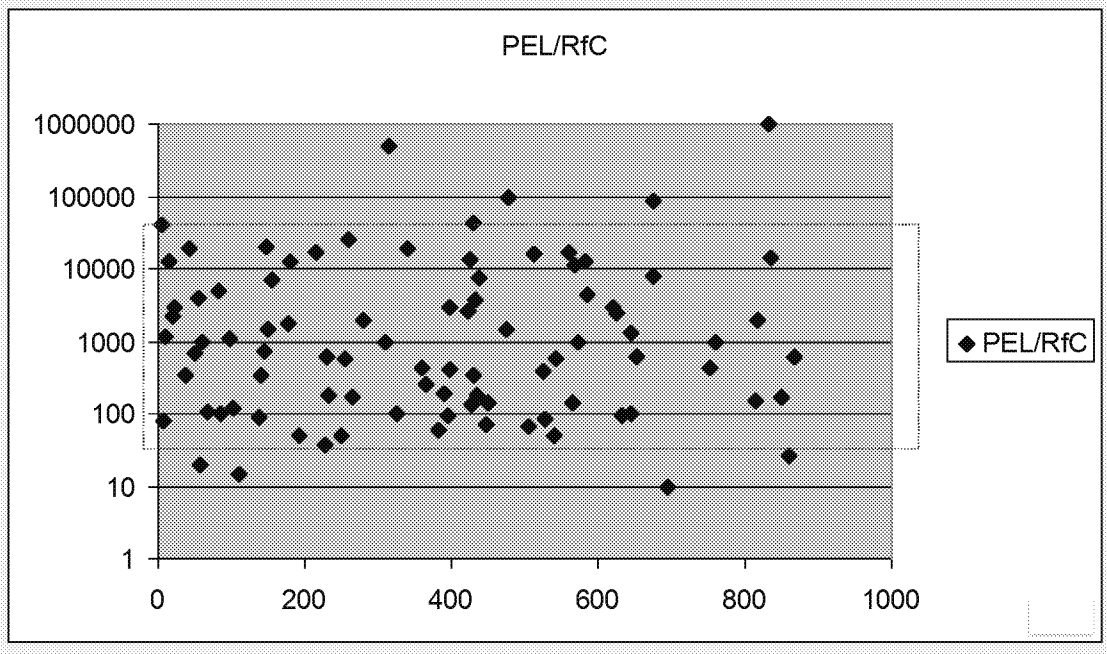
For an analogy, the "margin of exposure" is like a sign stretched across the Niagara River that tells kayakers there is a "waterfall acceptably far ahead," with no information about how close it is or how dangerous the drop; only a risk determination can shed light on those useful questions.

And even for cancer, the AMOUNT of risk that is/not acceptable is never mentioned. Neither the "Scoping" nor the "Problem Formulation" documents for 1-bromopropane have a SINGLE risk estimate or risk-based goal in them!

Straw man proposal: <u>For health effects that are serious or grave, a risk cannot be "reasonable" unless with at least 90% confidence, at least 95% of the exposed population shall face a lifetime excess risk of 1/50,000 or less.</u>

*This definition assumes "unreasonable risk" is a ceiling value: in other words, EPA shall ensure in the risk-management phase of TSCA that these risks are **never** to be exceeded—but when risk-reduction costs are low, it shall be EPA policy to lower unreasonable risks **further**.*

Most of the OSHA PELs are between 50 and 50,000 (!) times the EPA RfC



(2: risk and benefit underestimation)

(from current (2005) EPA Cancer Risk Assessment Guidelines

The linear default is thought to generally provide an upper-bound calculation of potential risk at low doses, for example, a 1/100,000 to 1/1,000,000 risk. This upper bound is thought to be public-health protective at low doses for the range of human variation, considering the typical Agency target range for risk management of 1/1,000,000 to 1/10,000, although it may not completely be so (Bois et al., 1995) if pre-existing disease or genetic constitution place a percentage of the population at greater risk from exposure to carcinogens. **The question of what may be the actual variation in human susceptibility is one that was discussed in general in the NRC (1994) report, as well as the NRC report on pesticides in children and infants (NRC, 1993b). NRC has recommended research on the question, and EPA and other agencies are conducting such research. Given the current state of knowledge, EPA will assume that the linear default procedure adequately accounts for human variation unless there is case-specific information for a given agent or mode of action that indicates a particularly susceptible subpopulation or lifestage, in which case the special information will be used.**

(from A. Finkel, chapter in **Low-Dose Extrapolation of Cancer Risks,** 1995)

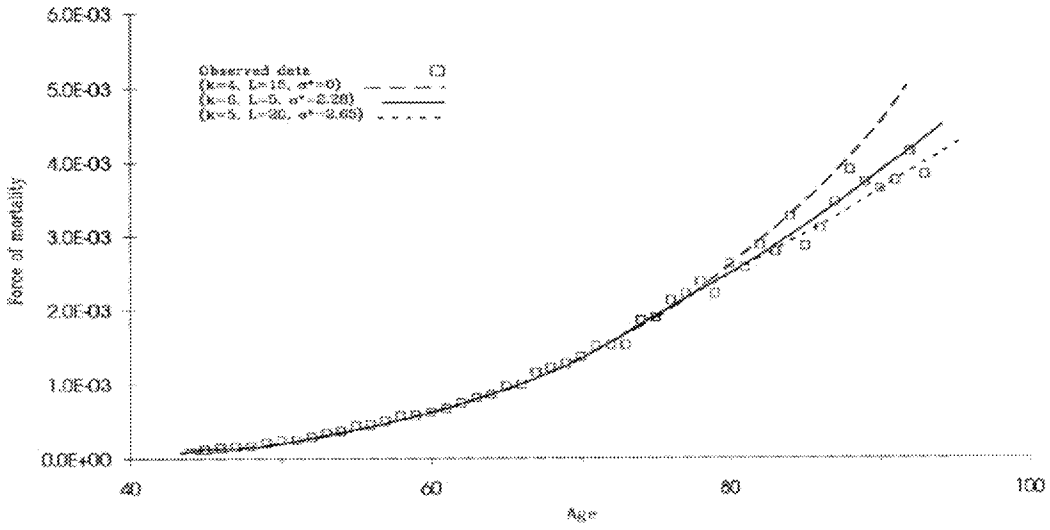


Figure 2. Comparison of three heterogeneity dynamics models, as applied to cohort data on colorectal cancer in all U.S. males born in 1890. The open squares represent the observed data relating the tumor-specific force of mortality to the age of the cohort. The dashed curve shows the fit to the data of a particular Armitage-Doll age-incidence function where susceptibility is assumed to be invariant. The solid and dotted curves show two models where susceptibility is allowed to vary lognormally across the population, with the optimal values of σ shown in the figure. Note the superior fit of the latter two models, both in terms of the log-likelihood values given in Figure 3 and in terms of their fit to the data in the last 8–10 years of the age distribution.

NAS "Science and Decisions, 2009

An assumption that the distribution is lognormal is reasonable, as is an assumption of a difference of a factor of between 10 and 50 between the median and upper 95th percentile people… *It is clear that the difference is significantly greater than the factor of 1, the current implicit assumption in cancer risk assessment.* …The committee recommends that EPA adopt a default distribution or fixed adjustment value for use in cancer risk assessment. **A factor of 25 would be a reasonable default value to assume as a ratio between the median and upper 95th percentile persons' cancer sensitivity.**


Consensus Report

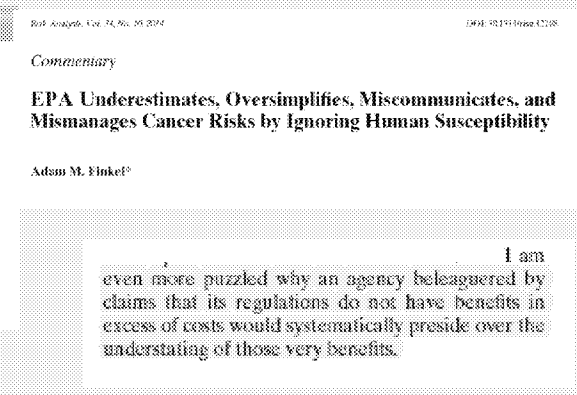
SCIENCE AND DECISIONS

Science and Decisions: Advancing Risk Assessment (2009)

Board on Environmental Studies and Toxicology

Topics:

Get the Report


Commentary

EPA Underestimates, Oversimplifies, Miscommunicates, and Mismanages Cancer Risks by Ignoring Human Susceptibility

Adam M. Finkel*

I am even more puzzled why an agency beleaguered by claims that its regulations do not have benefits in excess of costs would systematically preside over the understating of those very benefits.

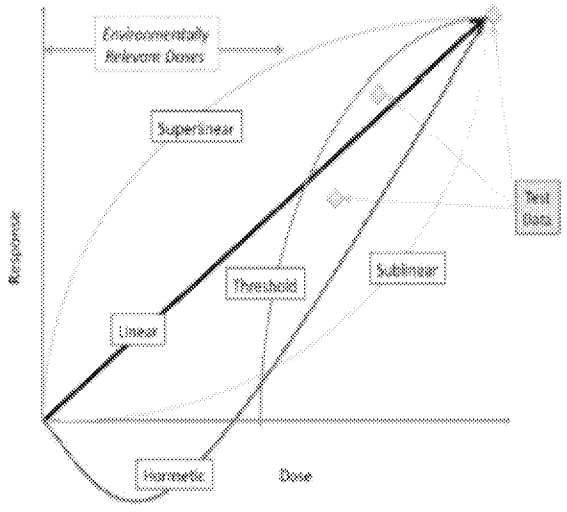


Fig 1. A stylized depiction of a hypothetical set of three exposure levels where adverse effects were seen ("test data") and how various dose-response models might fit the data acceptably well but have different implications for lower-dose risk.

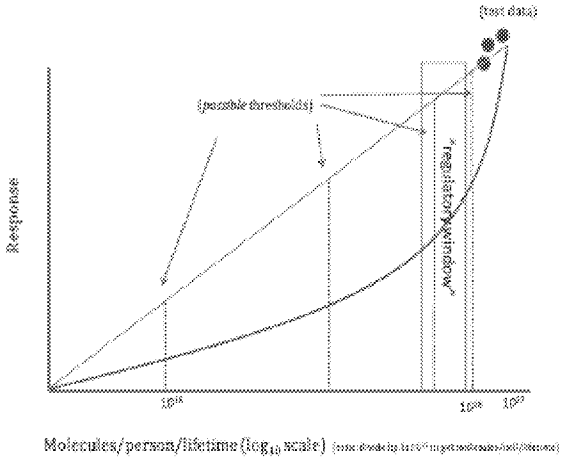


Fig 2. A different depiction of the same "test data," showing two possible locations of a dose-response threshold (the dashed vertical lines) that would have no practical relevance because no decision-maker is contemplating lowering exposures nearly to the point where the threshold occurs.

The "Trust Us, We're (Better) Scientists" Playbook of Manufactured Doubt:

Claim	Refutation
The substance "has a threshold," so it's somehow less/not important	Unless it is a "magic threshold"– one that appears within the narrow window between current exposures and desired exposures, this claim changes NOTHING about risk!
The substance is (or is alleged to be) non-genotoxic	Non-mutagens can be carcinogenic or otherwise toxic.
"Pay no attention to the dead mice/rats because humans are different"	Sometimes a very valid argument, WHEN data and theory support it plausibly.
No statistically significant epidemiology, so not "really" a carcinogen/toxicant	Epidemiology is great for rare diseases with potent environmental causes; otherwise, it can be "looking at Jupiter with binoculars."
If there is epidemiology, don't believe it "because confounding"	True confounding is much less common than skeptics claim.
Don't bother testing it because we know from structure-activity theory it is benign.	Embarrassing history of past mistakes.

"Invoke" Science as a Last Resort (?!):

(from 2005 (current) EPA Cancer Guidelines)

As an increasing understanding of carcinogenesis is becoming available, these cancer guidelines adopt a view of default options that is consistent with EPA's mission to protect human health while adhering to the tenets of sound science. Rather than viewing default options as the starting point from which departures may be justified by new scientific information, these cancer guidelines view a critical analysis of all of the available information that is relevant to assessing the carcinogenic risk as the starting point from which a default option may be **invoked if needed** to address uncertainty or the absence of critical information.

> EPA's Human Health Research Program is strategically aimed at providing the methods, tools, and data needed to improve risk assessments to protect public health. The primary goal of the program is to reduce reliance on default assumptions and simplified approaches used in risk assessments in the absence of conclusive data.

Therefore, EPA's stated goal of "reducing reliance on defaults" *per se* is problematic; it raises the question of why a scientific-regulatory agency would EVER want to reduce its reliance on those inferences that are supported by the most substantial theory and evidence.

This member of the Committee certainly endorses the idea of reducing EPA's reliance on *those defaults* that are found to be outmoded, erroneous, or correct in the general case but not in a specific case—but identifying those inferior assumptions is exactly what a system of departures from defaults, as recommended in the Red Book, in *Science and Judgment,* and in this report, is designed to do.

EPA should modify its language to make clear that across-the-board skepticism about defaults is not scientifically appropriate. This member urges EPA to delineate what evidence will determine how it makes these judgments, and how that evidence will be interpreted and questioned—and EPA's current policy (yet again) sidesteps these important tasks.

(from footnote in Ch. 6 of Silver Book)

A Proposed "Perfect Quid pro Quo":

Before freezing in place the status quo, and embarking on years of investigation into mechanism(s) of action, possible hormesis, showing of "manipulative causality," systematic review, etc., let's **bifurcate:**

1a. Estimate the amount of exposure reduction that would be necessary under the "all defaults are valid" assumptions;

1b. Estimate the (lesser) amount of exposure reduction that would be minimally necessary under *any* reasonable conclusions of a more "sophisticated" risk assessment;

1c: Mandate some amount of exposure controls between 1a and 1b levels.

2. THEN put the hazard onto the "gold-plated highway" and eventually see if the controls imposed under 1c were slightly too stringent or somewhat insufficient (at which point further controls would be required).

At least this would not hold the good hostage to the perfect.

Other ways to stop underestimating those benefits counted:

- Change the way EPA and others elicit "value of life" estimates: ask the right question, and do not bias downward by subtracting out any hint of altruism.
- Decrease the discount rate for benefits to 1%-3%, decreasing it further within an RIA for far-off consequences

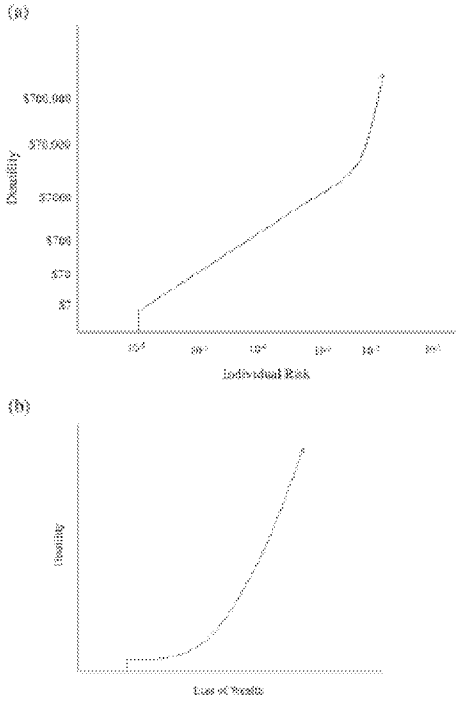


Figure 2 (a) One possible way to improve the treatment of individual risks: retain the de minimis region, but allow large risks to carry valuation that rises more steeply than linear as the probability of death becomes intolerably high. (b) One possible way to improve the treatment of individual costs: impose a de minimis region, and allow large costs to carry large, but not infinite, valuation.

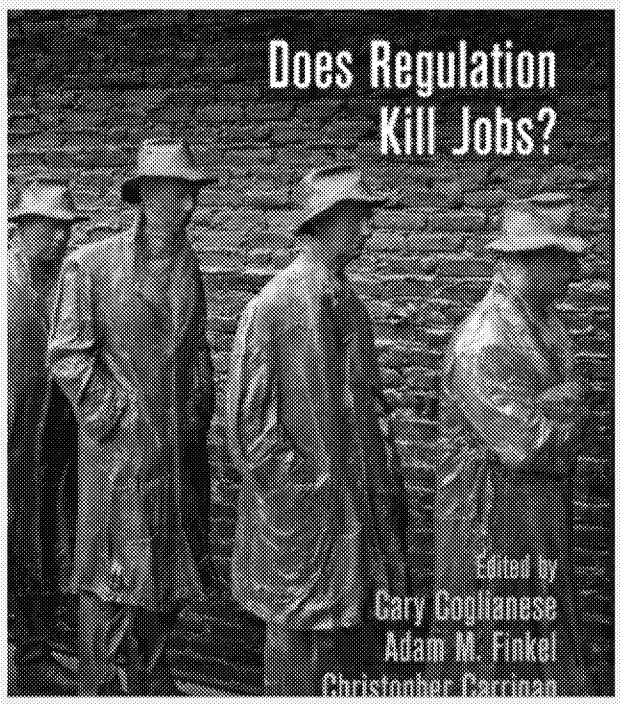
Full Sample	Total	Excluding ≤ $100 & ≥ $1 billion
N	733	637
Mean	$31,499,343	$18,416,134
Standard deviation	$180,126,601	$71,491,563
Median	$342,525	$632,456
5th percentile	$1	$1,080
95th percentile	$102,277,236	$100,000,000
Costs-first		
N	393	383
Mean	$34,774,369	$19,875,285
Standard deviation	$140,093,322	$70,641,746
Median	$830,455	$816,497
5th percentile	$1,772	$2,403
95th percentile	$141,421,356	$111,333,954
Lives-first		
N	340	254
Mean	$27,746,908	$16,215,918
Standard deviation	$217,273,233	$72,839,115
Median	$54,772	$329,141
5th percentile	$0	$362
95th percentile	$45,116,165	$68,352,063

Table 1. Distribution of Imputed Values of Prol

(from Finkel and Johnson, "The Limits Of Self-interest: Results From A Novel Stated-Preference Survey To Estimate The Social Benefits Of Life-prolonging Regulations." *Environmental Law,* **48(3)***:* 453-476, 2018.)

3. Ensuring that Benefits are Not Over-Estimated:

- Develop an inventory of every EPA use of a co-benefit, so that no one can credibly claim the same co-benefits are counted in more than one rulemaking;
- Account for the disbenefits (to mental and physical health) of *net* jobs eliminated by a rulemaking
- Account for new risks that are a *direct and inevitable consequence* of risk reduction (but beware the bogus "tradeoff")


Does Regulation
Kill Jobs?
Edited by
Cary Coglianese
Adam M. Finkel
Christopher Carrigan

4. Ensure that Hard-to-Quantify Costs are also Captured:

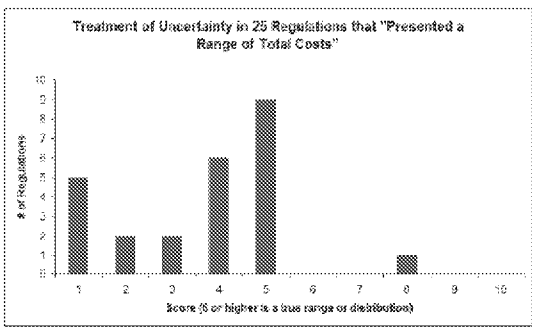
- Account for decreased innovation, managerial time, etc., using uncertainty bounds just as in #1 above

5. Don't Keep Overestimating Costs:

- Economic welfare must consider losses to losers and gains to winners (computable general equilibrium analysis)

(from A. Finkel, "The Cost of Nothing Trumps The Value of Everything: The Failure of Regulatory Economics to Keep Pace with Improvements in Quantitative risk Analysis." *Michigan Journal of Environmental and Administrative Law*, **4(1)**: 91-156.)

FIGURE 3. COST UNCERTAINTY SCORING OF EPA REGULATIONS PRESENTED IN THIS ARTICLE

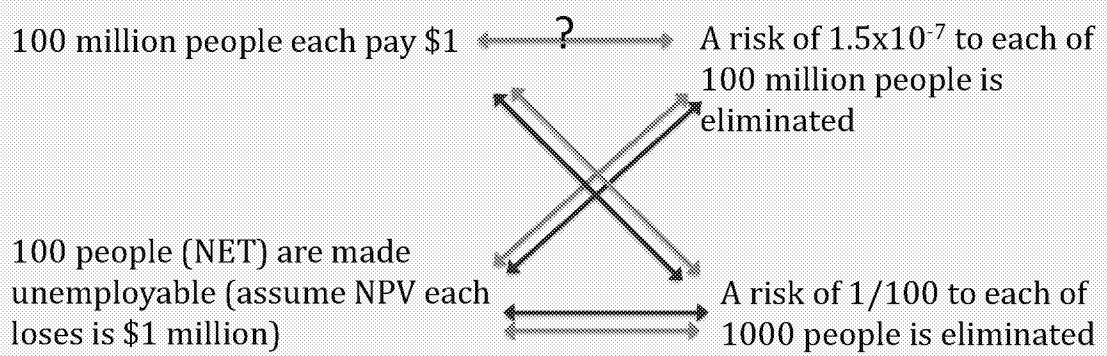


Try to Minimize Human Suffering rather than Maximize Net Benefit

[Suffering = *f* ("Intolerable Risk" OR "Intolerable Cost")]

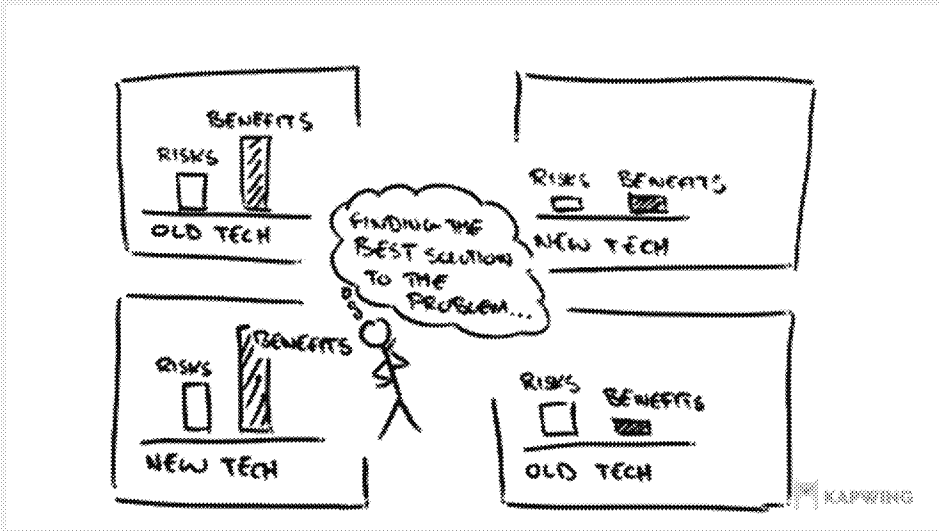
"Cost" "Benefit"

(Note– green arrows are cases where current CBA would **allow or dictate** reg'y *action*; red where current CBA would **preclude** action)



Of the four hypotheticals:

(horiz top)– green because C=$100MM and B= 15 lives or $135 MM. But either the Ci or the Bi could legit be rounded down to N times zero
(horiz bottom)– red because C=$100MM and B=10 lives or $90 MM. But 1000 suffer intol risk and only 100 suffer intol cost
(SW to NE)– green because C=$100MM and B=$135 MM– but should be RED because costs are intol and bens are de minimus
(NW to SE)– red because C=$100MM and B=$90MM– but should be GREEN because costs are de min and risks are intol.


BENEFITS
RISKS
OLD TECH
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FINDING THE BEST SOLUTION TO THE PROBLEM...
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